

## **REMARKS**

Of the 18 original claims, claims 1 and 16-18 are currently amended. Claims 2 and 4 have been cancelled. With this response, claims 1, 3, and 5-18 are now pending.

Applicant thanks Examiner Coe for the telephone interview dated February 4, 2003. Consistent with her suggestion, the independent claims have been amended to include an administration limitation. As discussed, the balanced effects of the inventive compositions allow beneficial results while reducing or eliminating the negative side effects possible from administration of either lactoferrin or beta-glucan individually. Daily administration is discussed at several sections of the specification, including paragraphs [0033] and [0056]. Various extended periods of time are discussed throughout the specification, including paragraph [0055]. The balanced effects obtained by administration of the inventive compositions are discussed many times throughout the specification, and in the Declaration by inventor Marcus Gohlke submitted on August 7, 2002. Accordingly, the amendments to the independent claims are consistent with the patent application's disclosure.

Applicant does not believe that any fees are due at this time; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to this document, the Commissioner is authorized to deduct the fees from Howrey Simon Arnold & White, LLP Deposit Account No. 01-2508 13479.0002.CPUS01 BNT.

### **I. Rejection under 35 U.S.C. § 102**

Claims 1, 4-6, and 12-14 were rejected under 35 U.S.C. § 102(e) as allegedly being

The '698 patent suggests dermocosmetic and pharmaceutical compositions for treating various hyperreactive skin conditions and allergies. The compositions comprise compounds having anti-radical, anti-inflammatory, and anti-allergic activities. Lactoferrin and beta-glucan are among the many various compounds described in the patent as being suitable for inclusion in the compositions. As the Examiner indicated in the Office Action, the '698 patent describes compositions in various liquid forms (column 6, lines 27-32). The '698 patent does not suggest preparation of solid compositions.

In order to expedite prosecution of the pending claims, claims 2 and 4 have been cancelled. Claim 1 has been amended to include the limitation that the composition is solid (the subject matter of dependent claim 2). As the '698 patent does not describe solid compositions comprising beta glucan and lactoferrin, it cannot anticipate independent claim 1 and its dependent claims.

Claims 1-2, 4-5, and 12-14 were rejected under 35 U.S.C. § 102(c) as allegedly being anticipated by U.S. Patent No. 6,406,897 B1 (hereinafter "the '897 patent").

The '897 patent describes proteins modified to improve their stability. The modification involves coupling the protein to a  $\beta$ -1,3-glucan branched with  $\beta$ -1,6-linkages. Lactoferrin is one of many proteins suggested as being suitable for such modification. The method for coupling involves oxidizing the glucan with periodates, adding protein to the oxidized glucan to form a Schiff base between a glucan aldehyde and an amino group on the protein, and adding a reducing agent (column 3, lines 9-17). As a result of this method, a single coupled molecule (glucan-protein) is formed.

The only stated claim is directed generally towards compositions comprising beta glucan

instant specification and Examples describe compositions where the two components are combined, but are not chemically reacted, coupled, or otherwise linked together. The '897 patent suggests a single coupled glucan-protein molecule, not a composition comprising beta glucan and lactoferrin.

Accordingly, claims 1-2, 4-5, and 12-14 should not be rejected as anticipated by the '897 patent.

Claims 2 and 4 have been cancelled. Applicant respectfully requests that the rejections of claims 1, 5-6, and 12-14 under 35 U.S.C. § 102 be withdrawn.

## **II. Rejection under 35 U.S.C. § 103**

Claims 1, 5, 7-11, and 16-17 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over the '698 patent

Independent claim 1 has been amended to incorporate the limitation of claim 2, namely that the composition is a solid. As stated by the Examiner, the '698 patent suggests various liquid compositions. Since the '698 patent generally described topical application of compositions to the skin and scalp, it would not be obvious to prepare a solid composition comprising beta glucan and lactoferrin, due to the difficulty in applying the solid composition in a topical manner.

Claims 1, 5-11, and 16-17 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over the '897 patent

As described above, the '897 patent does not teach compositions comprising beta glucan and lactoferrin. Rather, the '897 patent suggests modified proteins coupled to a glucan.

Lactoferrin is one of many proteins suggested as being suitable for such modification. The '897 patent does not suggest the claimed compositions comprising beta glucan and lactoferrin.

The Examiner indicated that it would be obvious to optimize the parameters of the '897 patent to arrive at the rejected claims. Applicant respectfully disagrees with this characterization. Optimizing the '897 patent would at best lead to a beta glucan - lactoferrin coupled molecule. The '897 patent does not suggest using each component separately (i.e. non-coupled). In fact, the '897 patent specifically provides the "coupling" modification as a means for improving the stability of the protein. One would therefore not be motivated to use glucan and protein (lactoferrin) separately, as no improvement in the protein's stability would be expected.

Claims 1-18 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 5,296,464, U.S. Patent No. 5,783,569, and U.S. Patent No. 5,670,138.

The Examiner indicated that based on the information in the references and the statements made by Applicant, the compositions do not produce unexpected results. Furthermore, the Examiner suggested that it seems that each ingredient is functioning in a manner that would be expected based on the known properties of each of the compounds.

As indicated in the previously filed Declaration, and in the graphic sent to the Examiner on January 13, 2003 (entitled "Synergistic effect of compositions comprising beta glucan & lactoferrin"), Applicant maintains that the selection and use of the two components in combination provides for long term benefits while avoiding negative side effects. Beta glucan and lactoferrin individually have both positive and negative effects when ingested. The two, when combined, promotes the positive effects while balancing long term potential risks. For

glucan promotes TNF- $\alpha$ , which leads to chronic inflammation and promotion of various disease processes. Beta glucan also promotes IL-6 production, impairing repair of vital tissue, and generally over-activates the immune system.

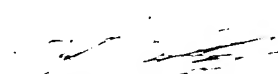
Claim 1 and its dependent claims describe compositions comprising both beta glucan and lactoferrin. Applicant has found this combination to be both beneficial and unexpected in its ability to provide sustained benefits while mitigating potential negative effects. Independent claims 16-18 provide for specific compositions found to be presently attractive as a lozenge.

Claims 2 and 4 have been cancelled. Accordingly, Applicant requests that the rejections of claims 1, 3, and 5-18 under 35 U.S.C. § 103 be withdrawn.

In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding objections and rejections are respectfully requested. All amendments are made in a good faith effort to advance the prosecution on the merits. Applicant respectfully submits that no amendments have been made to the pending claims for the purpose of overcoming any prior art rejections that would restrict the literal scope of the claims or equivalents thereof. Applicant reserves the right to subsequently take up prosecution of the claims originally filed in this application in continuation, continuation-in-part, and/or divisional applications.

The Examiner is encouraged to call the undersigned should any further action be required for allowance.

Respectfully submitted,

  
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